

(c) said implantation system incorporating an average particle size and average texture roughness to, in combination in an autogenous manner, substantially preclude migration of said particles from an injection site and achieve adequate guidance of fibroblasts such that a scar tissue pattern is developed that assumes a configuration that is generally in accordance with adjacent particle surfaces[.], said particles remaining in situ to form a permanent part of said implantation system.

REMARKS

In accordance with the proposed above amendments, claims 70-79, 81, 99 and 100 have been amended. Claims 70, 76 and 78-100 remain under consideration in the application, and no claim has been allowed.

In item 3 of the Examiner's Action, claims 77, 80, 93 and 99 have been rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative under 35 U.S.C. § 103, as being obvious over Berg et al (U.S. Patent 4 837 285). This rejection is respectfully traversed.

While Berg et al may at first appear quite relevant, further study reveals that their approach is fundamentally different from that of the present invention. Theirs is a collagen-based composition for augmenting soft tissue, most notably as a wound

dressing, but one which may also be used for implants, injectable formulations, etc. The material is soft and the beads may be of a size overlapping that of the particles of the present invention. However, the material of Berg et al differs fundamentally from that utilized in the present invention as it is clearly meant to and does become completely resorbed into the body thereby creating but a short-term temporary effect. In the abstract, at lines 3-4, their material is described as ". . . comprising resorbable collagen matrix beads . . ." The material of Berg et al is by no means intended to become encapsulated and remain in situ as part of a long-term or permanent soft tissue augmentation system, as is the case with the material of the present invention. All of applicants' claims require that the particulate material remain in situ to form part of an implant which is intended to provide long-term soft tissue augmentation. Thus, Berg et al represent an approach which differs fundamentally from that of the present invention.

Berg et al do not meet all of the limitations of the claims it is cited to anticipate and it is urged that no rejection under 35 U.S.C. § 102 can be sustained. Furthermore, it is believed that the resorbable Berg et al system cannot render applicants' system obvious inasmuch as the two represent different approaches and philosophies with respect to how the particulate material is used and its role in soft tissue augmentation. The resorbable material

of Berg et al would find no useful purpose in the particulate system of the present invention in which the particles are deliberately limited to materials that are not resorbed during the healing (scar tissue formation) process but which remain to become, by encapsulation, part of the augmentation material itself.

With regard to additional rejections under item 5, i.e., the rejection of claims 78, 79, 81-89, 91, 94, 96 and 97 under 35 U.S.C. § 103 based on Berg et al, it is believed that, too, cannot prevail based on the fundamental differences between Berg et al and of the present invention as explained above regardless of bead size or bead pore size.

The same may be said of the combination of Berg et al with Miyata et al (U.S. Patent 4 565 580). With respect to the latter, whether the collagen beads are substantially spherical or not still misses the fundamental point of the present approach.

The final enumerated rejection under 35 U.S.C. § 103 is applied to claims 81, 90, 92, 95 and 100 which are deemed unpatentable over Bucalo (U.S. Patent 4 197 846) or duPont (publication: NEN-TRAC MICROSPHERES). This rejection is respectfully traversed. Bucalo discloses injection of an absorbable viscous substance containing a plurality of solid bodies suspended therein into tissue for the purpose of enlarging proximate body tissue. Although a variety of materials can be used, the intent here as with Berg et al is that the injected

particulate material be eventually reabsorbed by the body albeit at a slower rate than the vehicle in which they are dispersed. Note, for example, column 3, line 12-20, where relatively hard ("... hardness of bone . . ."), reabsorbable particles are described. See also, for example, claim 1. This reference, like Berg et al, does not teach that the injected material become a permanent part of the implant growth which it promotes. Independent claims 81 and 100, as was the case with applicants' other claims, presently require this to be case regardless of size or surface roughness. The duPont article describes microspheres of uniform size having a diameter of 10 to 15 microns used as tracers to measure blood flow. This is clearly below the size contemplated for the micro particles of the present invention. Claim 81, for example, at subsection (b), requires a particle size between 30 and 3000 microns. With respect to claim 100, this size is "between 60 and 3000 microns", clearly outside the scope of the microspheres contemplated by duPont. The particles of the invention would not function in the "tracer mode" contemplated by duPont and the spheres of duPont would not function in the implants of the present invention. Spheres of 10 to 15 microns in diameter would be carried away from the injection site by the capillary system and would not remain in situ as is required for the micro particles of the present invention and the larger particles of the invention would not fit in capillaries. For the same reasons, the dependent

claims 90, 92 and 95 also include limitations not met nor rendered obvious by the cited art and, too, are believed patentably distinct.

In view of the above amendments, taken together with the remarks herein, applicants believe that their present claims represent a distinct step in the art and patentably distinguish over any of the art cited taken either singularly or in combination and consideration and early allowance of the claims is respectfully requested.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing copy of a letter, an Amendment under 37 CFR § 1.111 in response to an Official Action dated June 8, 1994, and a Petition for Extension of Time, in application Serial No. 08/052,414, filed on April 22, 1993, of Robert A. Ersek et al entitled "TEXTURED MICRO IMPLANTS" is being sent by facsimile transmission to: Attention: Examiner D. Brittingham, Art Unit 3308, Commissioner of Patents and Trademarks, Washington, D.C. 20231, on September 21, 1994.



Christine M. Zumwald
Secretary to C. G. Mersereau
Date of Signature: September 21, 1994